REMARKS

Reconsideration and allowance are respectfully requested. Applicants thank the Examiner for agreeing to interview and allowing Applicants to clarify technical features of this invention.

Claims 1, 3-4, 6-24 and 57-59 are pending. Claims 2 and 5 are cancelled by this amendment without disclaimer or prejudice to future prosecution of that subject matter. Claims 1, 3, 6 and 57-58 are amended.

Applicants thank the Examiner for indicating that claims 17-18 would be allowable if rewritten in independent form. All other claims currently stand rejected. Applicants traverse for the reasons stated below.

35 U.S.C. 112 – Written Description

Claims 1-17, 19-24 and 57-59 were rejected under Section 112, first paragraph, because it was alleged that they contain "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Applicants traverse.

_____The specification must convey with reasonable clarity to persons skilled in the art that applicant was in possession of the claimed invention as of the filing date sought. See *Vas-Cath v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997), emphasis added.

_____Applicants respectfully traverse because the specification clearly provides support for the presently claimed subject matter in compliance with the "written description" requirement of the first paragraph of 35 U.S.C. § 112.

The claimed invention is directed to a protocol for extraction of markers from two or more organisms in a sample and uses at least an oxidizing acid (e.g., nitrous acid) as the extraction reagent. See specification at page 8, lines 3-7. Prior to Applicants' inven-

tion, nitrous acid was used only to extract cell-wall associated carbohydrate markers of Streptococcal bacteria and was not used for other classes of markers because such harsh conditions would be expected to lead to destruction of these markers. See specification at page 2, line 7, to page 3, line 13. Consequently, it was believed that, for example, in response to a patient's complaint about her sore throat, two separate samplings, extractions, and tests would be required: one for viral infection and another for Streptococcal infection.

The specification teaches that a variety of markers (pages 8-9) from a broad spectrum of organisms (page 11) can be used in methods of the claimed invention. The specification provides clear and convincing working examples for the extraction of carbohydrate and protein markers from a representative number of viruses and bacterium. See, e.g., specification at pages 32-39. The extraction reagents used with Applicants' invention are described in the specification at pages 23-26. The detailed descriptions of suitable assay methods, extraction reagents, and biomarker targets fully support the breadth of the pending claims and clearly indicate to a skilled artisan that Applicants were in possession of the claimed invention. The specific markers include many that are well known to the skilled artisan and routinely measured in conventional single assay formats, so that a person of ordinary skill in the art will readily recognize that the specification teaches application of the extraction reagent of the subject invention to well known and cataloged markers.

In asserting a "written description" rejection, the initial burden of proof rests with the Examiner. Applicants urge that the Examiner has failed to meet that burden. The M.P.E.P. clearly states:

> The inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). **A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption.** See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). . . .The examiner has the initial burden of presenting **by a preponderance of evidence** why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97.

M.P.E.P. § 2163.04, emphasis added.

Applicants submit that the Examiner's suggestion on page 3 of the Action to limit the claims to markers of the specific organisms described in the working examples of the specification contradicts proper legal standards. M.P.E.P. §§ 2163-2163.07 sets forth the proper standard for determining whether an applicant has satisfied the "written description" requirement of the first paragraph of 35 U.S.C. § 112. A person of skill in the art would readily recognize from the original disclosure that Applicants invented the presently claimed subject matter. The function of this requirement is to ensure that a patent is granted to inventors who had possession, as of the filing date of the application, of the specific subject matter later claimed by them; how the specification accomplishes this is not material. *In re Smith*, 178 USPQ 620 (CCPA 1973). Therefore, the test for determining whether the "written description" requirement under the first paragraph of 35 U.S.C. § 112 is satisfied is whether the originally-filed specification reasonably conveys to a person having ordinary skill that Applicants had possession of the subject matter later claimed. *In re Kaslow*, 217 USPQ 1089 (Fed. Cir. 1983).

Favorable reconsideration is earnestly solicited.

35 U.S.C. 112 – Enablement

Claims 1-17, 19-24 and 57-59 were rejected under Section 112, first paragraph, because it was alleged that the specification "does not reasonably provide enablement for a method of measuring a plurality of organisms (two or more) in which the organisms may be any two or more organisms, or a method of measuring any two or more markers, or a method of measuring any one marker that is viral or protein, or a method of measuring a streptococcal group-specific antigen and any viral marker." Applicants traverse.

It appears that the Examiner is requiring the presence of working examples to enable the claims. On pages 4-5 of the Action, the Examiner admitted that the claims are enabled as to the four organisms that were tested in the working examples, but she alleged that the claims are not enabled for a plurality of organisms outside of the group of organisms tested in the working examples.

Applicants urge that the Examiner applied an incorrect legal standard. Applicants submit that the "enablement" prong of the first paragraph of 35 U.S.C. § 112 requires nothing more than objective enablement. Whether this is achieved by illustrative examples or by broad terminology is of no importance. *In re Marzocchi*, 169 USPQ 367 (CCPA 1971), emphasis added. Moreover, there is no requirement that Applicants provide a working example of their invention. See *In re Strahilevitz*, 212 USPQ 561, 563 (CCPA 1982), emphasis added. Here, working examples are provided and it would be unreasonable to require that each and every embodiment within the scope of the claims be present as a working example.

Applicants submit that the experimentation here is not undue because a skilled artisan engages in such experimentation on a routine basis. A large breadth of literature is available to the skilled artisan on markers that are appropriate for measuring the one or more organisms described in the specification (see pages 8-11). For most of these organisms, commercial antibodies are available for measuring at least one of the markers by immunoassay. The teachings in the specification at pages 23-26 enable this skilled artisan to select an extraction reagent suitable for use with a desired marker combination. The optimization of final reagent concentration is routine in the art of assay development. As admitted by the Examiner, the level of skill in the art is high and the art of assay development is mature. No evidence was presented by the Examiner to establish that routine matters such as those described above would require undue experimentation.

Applicants urge that the level of direction and guidance provided in the specification is sufficient for a skilled artisan to practice the claimed invention. The specification provides a range of concentrations for the nitrous acid extraction reagent plus a list of suitable surfactants including preferred ranges of concentrations. Finally, the working examples provide exact extraction reagent compositions suitable for extracting carbohydrate and protein markers from bacteria and viruses in the same sample from four different organisms. The Examiner provides absolutely no evidence on the record to suggest that this result can only be achieved with these four organisms. Applicants urge that based on the disclosure in the specification and, further in view of the high

state of relevant art, a person of skill in the art would be able to select the exact parameters of an extraction reagent suitable for two or more organisms in the same sample.

M.P.E.P. § 2164.01(a) enumerates a number of factors for determining whether experimentation is undue. Applicants urge that after considering all of these factors, the experimentation required for assay optimization of the claimed invention is not undue. In Applicants' specification there is considerable detail, direction, and guidance for the measurement of two or more organisms at the same time in a sample.

> Enablement is not precluded by the necessity for some experimentation such as routine screening, However, experimentation needed to practice the invention must not be undue experimentation. The key word is "undue," not "experimentation." *In re Wands,* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988).
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> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) and M.P.E.P. § 2164.06.
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> The test for enablement is whether one reasonably skilled in the art to make or use the invention from the disclosure in the patent coupled with information known in the art without undue experimentation. A patent may be enabling even though some experimentation is necessary. *United States v. Telectronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217 (Fed. Cir. 1988).
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> Favorable reconsideration is earnestly solicited.

35 U.S.C. 102 – Novelty

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Although Applicants believe claim 1 is novel for the reasons discussed in their previous response, to further prosecution of the application, this claim is amended by incorporating the limitations of nonrejected claim 5. Similarly, claims 57-58 are amended

to clarify that the organisms in the sample include at least (i) a gram positive bacterium and (ii) an organism that is a fungus, virus, or gram negative bacterium. The pending claims, according to the Examiner's interpretation of the cited references, incorporate at least one limitation not taught in the cited references and, therefore, the amendment is sufficient to overcome the rejections. The withdrawal of the 35 U.S.C. § 102 rejections is earnestly solicited.

As the Examiner previously considered the limitations added to claims 1 and 57-59 and the entry of this after-final amendment reduces the number of issues for appeal, entry of the claim amendments is proper. No new issues are raised and no further consideration is required.

Conclusion

Having fully responded to all of the pending objections and rejections contained in this Final Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit early Notice of same.

Respectfully submitted,

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